K112514

JAN - 9 2012

510(K) SUMMARY

In accordance with 21 CFR 807.92 the following summary of information is provided:

January 5, 2012

SUBMITTER:

Advanced Brain Monitoring
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PRIMARY CONTACT PERSON:

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SECONDARY CONTACT PERSON:

Dan Levendowski
President and Co-founder
Advanced Brain Monitoring, Inc.

DEVICE:

TRADE NAME: Apnea Risk Evaluation System (ARES™), Model 610

COMMON/USUAL NAME: ARES

CLASSIFICATION NAMES: 868.2375 Ventilatory Effort Recorder

PRODUCT CODE: MNR

PREDICATE DEVICE(S):

K111194 Apnea Risk Evaluation System (ARES), Model 610

K082968 ApneiCare Connection Center /Internet Analysis, ApneiCare, LLC

DEVICE DESCRIPTION:

The Apnea Risk Evaluation System (ARES™) includes a device called a Unicorder which records oxygen saturation, pulse rate, snoring level, head movement and head position, and airflow. Additionally, a physiological signal from the forehead used to stage sleep or respiratory effort signal obtained from an optional piezo respiratory effort belt can be acquired. The battery powered Unicorder provides sufficient capacity to record two nights of data. The device monitors signal quality during acquisition and notifies the user via voice messages when adjustments are required.

A standard USB cable connects the Unicorder to a USB port on a host computer when patient data is to be uploaded or downloaded. The USB cable provides power to the Unicorder during recharging from the host computer or from a USB wall charger. The Unicorder cannot record nor can it be worn by the patient when connected to the host computer or the wall charger.

Software, residing on a local PC or a physical or virtual server controls the uploading and downloading of data to the Unicorder, processes the sleep study data and generates a sleep study report. The ARES™ can auto-detect positional and non-positional obstructive and mixed apneas and hypopneas similarly to polysomnography. It can detect sleep/wake and REM and non-REM.

After the sleep study has been completed, data is transferred off the Unicorder and the Unicorder is prepared for the next study. The downloaded sleep study record is then processed with the ARES™ Insight software to transform the raw signals and derive and assess changes in oxygen saturation (SpO_2), pulse rate, head movement, head position, snoring sounds, airflow, and EEG or respiratory effort. The red and IR signals are used to calculate the SpO_2 and pulse rate. The actigraphy signals are transformed to obtain head movement and head position. A clinician can convert an auto-detected obstructive apnea to a central apnea based on visual inspection of the waveforms.

ARES™ Screener can predict pre-test probability of obstructive sleep apnea (OSA). The ARES™ can also assist the physician to identify patients who will likely have a successful OSA treatment outcome, including CPAP and oral appliance therapies. ARES™ can help identify patients who would benefit from a laboratory PAP titration.

INTENDED USE:

The Apnea Risk Evaluation System (ARES™), Model 610 is indicated for use in the diagnostic evaluation by a physician of adult patients with possible sleep apnea. The ARES™ can record and score respiratory events during sleep (e.g., apneas, hypopneas, mixed apneas and flow limiting events). The device is designed for prescription use in home diagnosis of adults with possible sleep-related breathing disorders.

TECHNOLOGY:

The ARES™ Model 610 being submitted is identical to the predicate ARES™ Model 610 (K111194) with the changes:

1. Modification to run ARES™ software from a cloud server, which may be a physical or virtual server, and is accessed using web-portal software.
2. Modification to ARES Insight software to improve filtering of the SpO_2 signal.
3. New claims, supported by published literature, are added to the ARES™ labeling and the ARES™ report:
    - The ARES report provides messages to help physicians plan for treatment and/or follow-up care.
    - ARES can help identify patients who would benefit from a laboratory PAP titration.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

COMPARISON TO PREDICATE DEVICES

The modified ARES™ Model 610 has the same intended use and fundamental scientific technology as the cleared ARES™ Model 610. All features are identical except those described in the table below.

Feature	Original Device (Model 610, K111194)	Modified Device (Model 610)	Reason for Change
Software Platform	All software operates on a local PC.	Software operates on a PC, or via a web portal.	Equivalent. The Portal Software was designed to emulate existing ARES software that communicates with the ARES Unicorder, allows for data entry, and manages the workflow of an ARES sleep study. The portal software and server configuration is similar to ApneiCare Connection Center /Internet Analysis which analyzes sleep data over the internet (K082968).
Derived Signals	• SpO2 • Pulse rate • Apneas and hypopneas • Hypopnea severity • Snoring loudness • Head movement and position • Sleep/wake • Stages rapid eye movement (REM) vs. non-REM	• SpO2 • Pulse rate • Apneas and hypopneas • Hypopnea severity • Snoring loudness • Head movement and position • Sleep/wake • Stages rapid eye movement (REM) vs. non-REM	Equivalent. Improved filtering has been added in the processing of the SpO_2 signal prior to identification of desaturation events. The raw signal acquired from the Unicorder is unchanged.

Feature	Original Device (Model 610, K111194)	Modified Device (Model 610)	Reason for Change
Saturation Accuracy	SpO_2 range / A_{rms} (%) 60-100% 2.4 90-100% 1.5 80- 90% 2.6 70- 80% 2.6 60- 70% 2.7 * Up to 32% of the reading may fall outside the listed error range	SpO_2 range / A_{rms} (%) 60-100% < 3.0 90-100% < 3.0 80- 90% < 3.0 70- 80% < 3.0 60- 70% < 3.0 * Up to 32% of the reading may fall outside the listed error range	Equivalent. The A_{rms} has changed due to the filtering changes but labeling will reflect specification of <3.0%. Accuracy in all ranges is less than 3.5% as recommended in Draft Guidance for Industry and FDA Staff - Pulse Oximeters - Premarket Notification Submissions [510(k)s] July 19, 2007.
Reports	Multiple report formats available.	Multiple report formats available. Treatment considerations messages are updated to help physicians plan for treatment and/or follow-up care and ARES can help identify patients who would benefit from a laboratory PAP titration.	Equivalent. The new statement is based on and supported by studies described in Section 20. The treatment messages are optional, and are presented in a report generated after the signals have been reviewed by the interpreting physician. The treatment consideration messages are not an automated diagnosis, but assist the physician in providing standard text for common messages in their reports. These messages are derived from published literature.

SUMMARY OF NON-CLINICAL TESTS:

Support for the substantial equivalence of the ARES™ Model 610 was provided as a result of risk management and software validation, which confirmed.

- All features of the ARES™ Model 610 were compliant with the system level requirements.
- The ARES™ software operates properly from a cloud server which is accessed using web-portal software.

SUMMARY OF CLINICAL TESTS:

The filtering changes to the SpO_2 signal were validated by analysis of clinical data previously acquired in two clinical studies. The first study analyzed original breathe down data and demonstrated steady-state accuracy is equivalent before and after implementation of the filtering changes. The second study analyzed breath hold data to evaluate performance of ARES™ during dynamic SpO_2 changes, as are typical in sleep disordered breathing. Both studies confirmed that that the accuracy of the ARES™ after the implementation of the filtering changes is equivalent to the original ARES™ accuracy.

Evaluation of published literature was also used to support the new claims and report messages introduced for ARES™.

CONCLUSION:

The conclusions drawn from the nonclinical and clinical tests demonstrate equivalent performance of the Apnea Risk Evaluation System (ARES™), Model 610 and the legally marketed devices. The Apnea Risk Evaluation System (ARES™), Model 610 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Brain Monitoring, Incorporation
C/O Ms. Adrienne Lenz
Regulatory Affairs Consultant
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JAN - 9 2012

Re: K112514
Trade/Device Name: Apnea Risk Evaluation System (ARES)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: December 29, 2011
Received: January 3, 2011

Dear Ms. Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

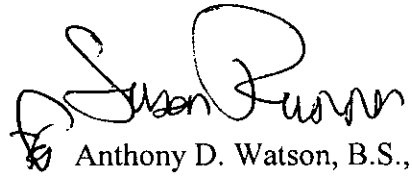
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Apnea Risk Evaluation System (ARES)

Indications for Use:

The Apnea Risk Evaluation System (ARES™), Model 610 is indicated for use in the diagnostic evaluation by a physician of adult patients with possible sleep apnea. The ARES™ can record and score respiratory events during sleep (e.g., apneas, hypopneas, mixed apneas and flow limiting events). The device is designed for prescription use in home diagnosis of adults with possible sleep-related breathing disorders.

Prescription Use_X_ AND/OR Over-The-Counter Use__

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112514